

REMARKS

I. Amendments to Claims

Applicant has herein amended claims 2, 9, and 16. Accordingly, claims 2, 9, and 16 are pending. Applicant submits that the amendments are fully supported by the specification as filed. For example, the amendments to the claims are supported at page 5, lines 15-19, and page 7, lines 1-5, of the specification as filed.

II. Restriction Requirement

In the Office Action dated May 5, 2009, the Examiner recited that restriction to one of the following inventions is required under 35 U.S.C. 121 and 372, as follows:

Group I, claims(s) 1, 3, 4, 10, 11, 17 and 18, drawn to *methods and processes for making TBO dyes and derivatives*, classified in class 514, subclass 297;

Group II, claim(s) 6, 7, 8, 13, 14, 15, and 20-22, drawn to a *methods of treating dysplastic tissues with TBO dyes*, classified in class 424, subclass 9.7;

Group III, claims 2, 9, and 16, drawn to compositions of TBO dyes, classified in class 514, subclass 297;

Group IV, claims 5, 12, and 19, drawn to methods of diagnosing dysplastic tissues with TBO dyes, classified in class 424, subclass 9.2; and

Group V, claim 23, drawn to a method for analyzing TBO dye products by HPLC, classified in class 506, subclass 6.

In response, Applicant has elected the claims directed to Group III, which are claims 2, 9, and 16, and has withdrawn claims 1, 3, 4, 10, 11, 17, 18, 6, 7, 8, 13, 14, 15, 20-22, 5, 12, 19, and 23. However, this election and accompanying withdrawal is with traverse. Applicant further reserves the right to file a continuation application and/or divisional application including any and all of the withdrawn claims and/or file additional claims that incorporate the subject matter of the withdrawn claims.

Applicant respectfully disagrees with the Examiner's position set forth in the Office Action and as follows in part:

"The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1, because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reason: Under the lack of unity rules, unity of invention exists only when there is a technical feature relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The "contribution over the prior art" is considered with respect to novelty and inventive step. Here, the only corresponding technical feature between the different inventions is the TBO dye. Burkett discloses in WO 99/25388, on pages 4-6, the TBO dye compositions claimed. The corresponding special technical feature therefore lacks novelty and there is no contribution over the prior art that the corresponding special technical feature makes."

Applicant submits that the group of inventions is linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding technical feature ("those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art"). In the Office Action, the Examiner alleges that the "only corresponding technical feature between the different inventions is the TBO dye. Burkett discloses in WO 99/25388, on pages 4-6, the TBO dye compositions claimed. The corresponding special technical feature [TBO claimed] therefore lacks novelty and there can be no contribution over the prior art that the

corresponding technical feature makes . . ." Applicant respectfully disagrees.

Applicant submits that nowhere in WO 99/25388 to Burkett ("Burkett" - Applicant's own application) does it teach the "TBO dye" as presently claimed. In the subject application, the TBO dye claimed is peak 8 being at least 73% by weight of the total organic dye content of the composition (claim 2); peak 6 being at least 73% by weight of the total organic dye content of the composition (claim 9); peak 8 and peak 6 being at least 70% by weight of the total organic dye content of the composition.

However, on pages 4-6 Burkett recites ". . . in the TBO compositions of the prior art, a typical one which is represented in Fig. 1, the compounds represented by peaks 1-4 were present in relatively higher amounts than those of the present invention (see Fig. 2) and the compounds represented by peaks 5-8 were present in relatively lower amounts . . ." (page 6, of Burkett). Applicant submits that neither Figs. 1 nor 2 of Burkett teach the compositions presently claimed.

Applicant submits that Fig. 1 of Burkett discloses a greater amount of impurities, i.e., a large amount of impurities (i.e., peaks 1-5). In addition, referring to Fig. 2, Applicant submits that it does not teach that peak 8 is at least 73% by weight of the total organic dye content of the composition; nor that peak 6 is at least 73% by weight of the total organic dye content of the composition; nor that peaks 6 and 8 are at least 70% by weight of the total organic dye content of the composition, as presently claimed. For example, Fig. 2 in Burkett teaches that peak 6 has an area of 41.88, peak 7 has an area of 112.27, and peak 8 has an area of 270.77. Even if the percentages by weight of each of the peaks were extrapolated from the areas of the peaks in Fig. 2, it would not disclose the compositions of the present invention, i.e., it would not disclose that peak 6 has the greatest percentage by weight of all peaks, or that peak 8 is specifically at least 73% by weight of the composition as claimed. For example, the area of peak 6 in Fig. 2 is much less than the area of, for example, peak 7. Accordingly, Applicant submits that the TBO dye claimed is novel over Burkett.

In addition, Applicant submits that the methods claimed in the subject application are novel over Burkett. For example, Burkett does not disclose the method as recited in claim 1, namely, Burkett does not teach or suggest combining *N,N*-dimethyl-*p*-phenylenediamine (or *N*-methyl-*p*-phenylenedimine) with *o*-toluidine to form an indamine as presently claimed. In Burkett, thiosulfate ions are added to the oxidized *N,N*-dimethyl-*p*-phenylenediamine to form the first intermediate, 2-amino-5-dimethylaminophenyl thiosulfonic acid. Thereafter, *o*-toluidine is added to the 2-amino-5-dimethylaminophenyl thiosulfonic acid. Applicant submits that the foregoing reversal of steps produces the novel TBO dye products having a large percentage of peak 8 and/or peak 6 as presently claimed. In fact, on page 16 of the subject application, it recites in relevant part, "The procedure for manufacturing the present TBO composition is a modification of previously known methods for producing TBO products. More particularly, the modification entails the reversal of the second and third steps described in the manufacture described by Burkett in U.S. Patent 6,194,573 [continuation-in-part of Burkett]. The reversal of steps, whereby *N,N*-dimethyl-*p*-phenylenediamine and *o*-toluidine in a stabilized solution are mixed prior to introducing a

source of sulfur-containing nucleophile, results in an entirely unexpected composition of TBO." As such, and as the subject application itself recites, the TBO dye is novel over Burkett. This is because the methods (as claimed) used to produce the TBO dye of the subject application are different than those disclosed in Burkett. In addition, the resultant dye products are different than those disclosed in Burkett.

Accordingly, Applicant submits that that the claims do share a special technical feature (novel TBO compositions and methods to produce thereof) and are thus linked within the meaning of PCT Rule 13.2, and therefore the restriction requirement should be withdrawn.

CONCLUSION

The Commissioner is hereby authorized to charge any additional fees necessary to Deposit Account 10-0440, or to credit any overpayment to the same.

Respectfully submitted,

Date: June 8, 2009



Manali V. Dighe, Esq.
Registration No. 56, 856
JEFFER MANGELS BUTLER & MARMARO LLP
1900 Avenue of the Stars
Seventh Floor
Los Angeles, CA 90067
310-203-8080
Customer No. 24574